FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE GABAPENTIN PATENT LITIGATION	MDL Docket No. 1384 Master Civil Action No. 00-2931 **This Filing Applies To:** Purepac Defendants C.A. No. 00-CV-2931 (FSH) C.A. No. 00-CV-3522 (FSH) Teva Defendants C.A. No. 00-CV-4168 (FSH) C.A. No. 00-CV-4589 (FSH) IVAX Defendants C.A. No. 00-CV-6073 (FSH) C.A. No. 01-CV-0193 (FSH) C.A. No. 01-CV-1537 (FSH) Eon Defendants C.A. No. 01-CV-2194 (FSH) **ORDER & OPINION** Date: May 12, 2011

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HOCHBERG, District Judge:

This matter comes before the Court on the sixteen motions in limine filed by the parties to the above-captioned action. The Court has reviewed the parties' submissions pursuant to Fed. R. Civ. P. 78.

Plaintiffs bring claims for infringement of U.S. Patent No. 6,054,482, entitled "Lactam-Free Amino Acids" (the "'482 Patent"). The '482 Patent discloses the manufacturing process for a substantially lactam-free form of gabapentin.[1]

This Court presumes familiarity with the facts of this case, which have been set forth repeatedly over the eleven year history of this action.[2]

This action is set to proceed to a jury trial on May 16, 2011.

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[1] Claim 7 of the '482 Patent claims:

> A stable and pure pharmaceutical composition in unit dry medicinal dosage form consisting essentially of:
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> (I) an active ingredient which is gabapentin in the free amino acid, crystalline anhydrous form containing less than 0.5% by weight of its corresponding lactam and less than 20 ppm of an anion of a mineral acid and
>
> (ii) one or more pharmaceutically acceptable adjuvants that do not promote conversion of more than 0.2% by weight of the gabapentin to its corresponding lactam form when stored at 25 s[degree]s C and an atmospheric humidity of 50% for one year.

[2] See e.g., In re Gabapentin Patent Litig., No. 00 Civ. 2931 (FSH), Opinion at 1-10 (D.N.J. Aug. 27, 2009) (Dkt. No. 683).

DISCUSSION

I. OFF-LABEL PROMOTION OF NEURONTIN AND EFFICACY OF GABAPENTIN

Plaintiffs move to exclude evidence and arguments relating to (1) off-label promotion of Neurontin and (2) Gabapentin's effectiveness in treating off-label conditions.[3]

Defendants move to exclude evidence and arguments contrary to prior courts' findings on these issues based on the doctrine of collateral estoppel.[4]

A. The Unclean Hands Defense

Plaintiffs argue that all of the evidence at issue on these motions should be excluded because this Court struck Defendants' "unclean hands" defense. In striking the affirmative defense, this Court noted that "[i]n the context of patent litigation, assertions of unclean hands have typically succeeded only in situations in which the misconduct related in some way to the procurement of the particular patent in question." In re Gabapentin Patent Litig., MDL No. 00-2931 (FSH), Dkt. No. 683 at 14-16 (D.N.J. Aug. 27, 2009) (citing MedPointe Healthcare, Inc. v. Hi-Tech Pharmacal Co., Inc., 380 F. Supp. 2d 457, 465-66 (D.N.J. 2005); Monsanto Co. v. Rohm & Haas Co., 456 F.2d 592, 594 n.3 (3d Cir. 1972); Republic Molding Corp. v. BW Photo Utilities, 319 F.2d 347, 351 (9th Cir. 1963)). This Court left open the possibility that evidence relevant to the defense might be admissible at a later stage of the litigation, mentioning potential

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[3] These motions are labeled as Plaintiffs' motions in limine numbers one and two, respectively. Included among the evidence Plaintiffs seek to exclude are the May 13, 2004 information filed in United States v. Warner-Lambert Co. (D. Mass.), the jury verdict and findings of fact and conclusions of law filed in Kaiser Foundation Health Plan v. Pfizer, Inc., No. 04-10739 (PBS) (D. Mass.) and the evidence related to the allegations in In re Neurontin Marketing and Sales Practices Litigation, MDL No. 02-1390 (FSH) (D.N.J.).

[4] This motion is labeled as Defendants' motion in limine number eight.

applications for equitable relief as an example.[5] In re Gabapentin Patent Litig., Dkt. No. 683 at 17 n. 20. Nothing in this Court's August 27, 2009 opinion can be read to bar the introduction of this evidence at trial.

B. Obviousness of the '482 Patent

Defendants seek to admit the evidence at issue as relevant to the obviousness of the '482 Patent.

"Under 35 U.S.C. § 103(a), a claimed invention is unpatentable if the differences between it and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the pertinent art." Ormco Corp. v. Align Tech., Inc., 463 F.3d 1299, 1306 (Fed. Cir. 2006).

"'[S]econdary considerations [such] as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented' and 'may have relevancy' as indicia of obviousness." Id. at 1311 (quoting Graham v. John Deere Co., 383 U.S. 1, 17-18 (1966)).

"In order to overcome a finding of obviousness by demonstrating commercial success, '[a] nexus between commercial success and the claimed features is required.'" Therasense, Inc. v. Becton, Dickinson & Co., 593 F.3d 1289, 1299 (Fed. Cir. 2010) (quoting Brown & Williamson Tobacco Corp. v. Philip Morris Inc., 229 F.3d 1120, 1130 (Fed. Cir. 2000)).

Plaintiffs plan to offer evidence as to the commercial success of and long felt need for Neurontin as part of their defense against the allegation that the '482 Patent is invalid because of

[5] To the extent any party is seeking equitable relief, all evidence must be introduced at trial. This Court will not hold a subsequent fact hearing at which this evidence would be considered.

obviousness. Plaintiffs' off-label marketing of Neurontin is relevant to these claims insofar as the jury may infer that the marketing of the product was part of the cause of this commercial success and undermines the idea that there was a long felt need for Neurontin.[6] See Brown & Williamson Tobacco Corp. v. Philip Morris, Inc., 229 F.3d 1120, 1130 (Fed. Cir. 2000) ("ample evidence" to rebut the nexus between the features of the patented product and commercial success where marketing, packaging and promotional offers were the cause of much of the product's success); see also Ritchie v. Vast Res., Inc., 563 F.3d 1334, 1336 (Fed. Cir. 2009) ("The commercial success of a product can have many causes unrelated to patentable inventiveness; for example, the commercial success of an 'invention' might be due not to the invention itself but to skillful marketing of the product embodying the invention.").[7]

C. Damages

Defendants also seek to admit the evidence at issue as relevant to damages.

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[6] Plaintiffs argue that the '482 Patent is a composition patent and thus is valid for all potential uses of Neurontin. Defendants may argue at trial, however, that the success of Neurontin was due not to any potential use but to unlawful promotion engaged in by the Plaintiffs.

[7] Plaintiffs rely on Continental Can Company v. Monsanto, 948 F.2d 1264 (Fed. Cir. 1991), but this case is not too the contrary. In Continental Can, the Federal Circuit wrote that "[i]t is not necessary, however, that the patented invention be solely responsible for the commercial success, in order for this factor to be given weight appropriate to the evidence, along with other pertinent factors." Id. at 1273. While this suggests that promotional efforts – including off-label promotion – are not decisive as to the commercial success factor, it does not indicate that evidence of such efforts should be excluded from the evidentiary record.

A patent holder, upon a finding that a patent is valid and infringed, is entitled to recover "damages adequate to compensate for the infringement, but in no event less than a reasonable royalty." 35 U.S.C. § 284.

1. Reasonable Royalty

A reasonable royalty "may be based upon an established royalty, if there is one, or if not, upon the supposed result of hypothetical negotiations between the plaintiff and defendant. The hypothetical negotiation requires the court to envision the terms of a licensing agreement reached as the result of a supposed meeting between the patentee and the infringer at the time infringement began." Rite-Hite Corp. v. Kelley Co., 56 F.3d 1538, 1554 (Fed. Cir. 1995) (internal citations omitted).

The calculation of a reasonable royalty also depends upon the application of several factors, set forth in Georgia-Pacific Corporation v. U.S. Plywood Corporation, 318 F. Supp. 1116 (S.D.N.Y. 1970), to the evidence at hand. One of those factors is "[t]he portion of the realizable profit that should be credited to the invention as distinguished from non-patented elements, the manufacturing process, business risks, or significant features or improvements added by the infringer." Id. at 1120. Plaintiffs' off-label promotion is just such a "non-patented element," and Defendants may argue that this promotion is relevant to the jury's calculation of a reasonable royalty. Plaintiffs do not cite any cases that address the relevance of such evidence to a reasonable royalty calculation and thus have waived any legal argument based upon case law.

2. Damages Based on Illegal Activity

"It is beyond dispute that [a plaintiff] cannot recover lost profits that are 'predicated on the completion of illegal activity.'" AlphaMed Pharms. Corp. v. Arriva Pharms., Inc., 432 F.

Supp. 2d 1319, 1348 (S.D. Fla. 2006) (quoting Carruthers v. Flaum, 365 F. Supp. 2d 448, 470 (S.D.N.Y. 2005)).

Plaintiffs argue that the sale of Neurontin is legal, as is the practice of physicians writing off-label prescriptions; the criminal conviction for illegal marketing of Neurontin, they contend, is only tangentially related to the subject matter at issue in this case.

This argument is unpersuasive as a bases to bar admission of evidence. While the sale of Neurontin and the writing of off-label prescriptions are not illegal, the off-label marketing Plaintiffs engaged in is illegal, which is why they pled guilty to the charges in United States v. Warner-Lambert Co. (D. Mass.).

In AlphaMed, the court considered a case in which the plaintiff attempted to prove its lost profits resulting from defendants' tortious interference with their business. The plaintiff based some of its projected profits on the sale of a product for what it viewed as unregulated uses. Id. at 1347-48. The court held that the plaintiff was not entitled to lost profits on the basis of those projections because such sales would have, in fact, been illegal. Id. Similarly, if Defendants can prove that some portion of Neurontin sales are attributable to illegal promotion, then the jury may consider that evidence as one of the many complex factors it will weigh in calculating the appropriate damages in this case.[8]

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[8] Plaintiffs also argue that any illegal activity they have been found to have engaged in is irrelevant because it occurred before 2004, when Defendants' began selling their generic gabapentin products. In her findings of fact and conclusions of law, filed in Kaiser Foundation Health Plan v. Pfizer, Inc., No. 04-10739 (PBS) (D. Mass.), Judge Saris held that the illegal off-label promotion did not end until December 2004, and Defendants have indicated that they intend to argue that the effects of the illegal conduct extended beyond that time frame. While Plaintiffs may argue that the timing of the illegal conduct at issue limits the impact of the evidence Defendant seeks to admit, this argument does not render that evidence inadmissible.

C. Collateral Estoppel

Defendants' seek to bar Plaintiffs from arguing (1) that Pfizer did not fraudulently promote Neurontin for off-label uses; (2) that scientific evidence demonstrates that Gabapentin is effective for off-label uses; and (3) that Pfizer's illegal promotion of Neurontin did not cause sales of gabapentin products, all on the basis of collateral estoppel.[9]

"[T]he standard requirements for collateral estoppel...[are] '(1) the identical issue was previously adjudicated; (2) the issue was actually litigated; (3) the previous determination was necessary to the decision; and (4) the party being precluded from relitigating the issue was fully represented in the prior action.'" Henglein v. Colt Indus., 260 F.3d 201, 209 (3d Cir. 2001) (quoting Raytech Corp. v. White, 54 F.3d 187, 190 (3d Cir. 1995)).

Defendants rely upon the Information filed in United States v. Warner-Lambert Co. (D. Mass.) and the verdict and decision in the Kaiser case. With respect to the criminal conviction for off-label marketing, Plaintiffs cannot claim that the conduct that was the basis of their guilty plea did not occur. However, to the extent that Kaiser addresses Plaintiffs' off-label promotion and fraudulent marketing in violation of RICO and California's Unfair Competition Law, Defendants have not established the first element of collateral estoppel: that those issues are identical to the issues in this case. While the findings in those cases may weigh on the questions put to the jury here – as set forth above – Defendants have not presented a basis upon which to preclude Plaintiffs from offering argument and evidence in rebuttal. See Tonka Corp. v. Rose Art Indus., 836 F. Supp. 200, 211 (D.N.J. 1993) ("Issue preclusion does not extend to collateral

[9] Plaintiffs have made clear that they only intend to offer this evidence as part of their rebuttal case.

issues nor to matters inferred from the judgment."). Essentially, Defendants are permitted to use the evidence of Plaintiff's conduct but they cannot bar Plaintiff from attempting to rebut that evidence, except that Plaintiffs are estopped from denying their guilty plea and the factual basis for that plea.[10]

II. SILICON DIOXIDE IN DEFENDANTS' GABAPENTIN CAPSULES

Plaintiffs move to exclude evidence and arguments that Purepac's capsules do not infringe because they contain silicon dioxide.[11] On April 25, 2011, this Court issued an Opinion & Order concluding, inter alia, that the silicon dioxide used in Purepac's capsules is contained in the capsule shell – because Purepac had so conceded on an earlier motion filed in this case – and is, therefore, not an adjuvant as that term is used in Claim 7. In light of that ruling, Plaintiffs' motion on this point is moot.

III. EVIDENCE CONTRARY TO DEFENDANTS' DISCOVERY POSITIONS

Plaintiffs move to exclude evidence contrary to the positions Defendants took in discovery with regard to two issues: (1) the construction of the "but for" world as it is relevant to lost profits damages and (2) Purepac's stability storage contentions.[12]

Federal Rule of Evidence 403 provides that "[a]lthough relevant, evidence may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice,

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[10] Should Defendants feel it is necessary, they may reserve time for a "sur-rebuttal" portion of their case, to follow Plaintiffs' rebuttal case. Should they choose to utilize a "sur-rebuttal," Defendants will be permitted to put in evidence on these issues only.

[11] This motion is labeled as Plaintiffs' motion in limine number three.

[12] This motion is labeled as Plaintiffs' motion in limine number four.

confusion of the issues, or misleading the jury, or by considerations of undue delay, waste of time, or needless presentation of cumulative evidence." Fed. R. Evid. 403.

"In considering whether the exclusion of evidence is an appropriate sanction for failure to comply with discovery duties, we must consider four factors: (1) the prejudice or surprise of the party against whom the excluded evidence would have been admitted; (2) the ability of the party to cure that prejudice; (3) the extent to which allowing the evidence would disrupt the orderly and efficient trial of the case or other cases in the court; and (4) bad faith or wilfulness in failing to comply with a court order or discovery obligation." Nicholas v. Pennsylvania State Univ., 227 F.3d 133, 148 (3d Cir. 2000).[13]

Plaintiffs' briefs fail to address the relevant factors in seeking to exclude evidence as a discovery sanction and thus Plaintiffs have not carried their burden on this motion.

Equally important, this motion is untimely. The deadline for raising expert discovery disputes was September 13, 2010. Plaintiffs' delay in seeking this relief is wholly unjustified in light of the exceptional length of time devoted to discovery during the eleven year pendency of this action. Every issue in this case has been found out, digested and re-digested over this long period; to seek what amounts to discovery sanctions, styled as a purported motion in limine, at this late date us bit a proper use of the motion in limine.[14]

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[13] The Federal Circuit applies substantially the same factors. See Chimie v. PPG Indus., 402 F.3d 1371, 1381 (Fed. Cir. 2005) (considering the factors enumerated by the Third Circuit).

[14] Moreover, there is no injustice in denying Plaintiffs' motion to exclude this evidence.

On the issue of construction of the "but for" world, Plaintiffs complain that Defendants are "newly" arguing that Purepac might have relinquished its first-filer exclusivity to allow Apotex or others who might have sold non-infringing alternatives to enter the "but for" market. Defendants raised the issue of relinquishment and selective waiver of Purepac's first-filer

IV. ADVICE OF COUNSEL AND POLICIES OF NON-INFRINGEMENT

Plaintiffs seek to exclude evidence that the Teva and IVAX Defendants relied on advice of counsel or followed a company policy of non-infringement in developing their gabapentin products.[15] Plaintiffs argue that because Teva and IVAX have not asserted an advice of counsel defense, they should not now be able to rely on the advice of counsel in defending this suit.[16]

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exclusivity in interrogatory responses as early as November 2009. Plaintiffs cannot legitimately claim surprise when they had notice of this issue eighteen months ago.

Plaintiffs also seek to exclude Purepac's argument that the storage conditions used in generating Purepac's stability data are substantially different than those specified in the patent. Plaintiffs' experts used Purepac's data in reaching some of their infringement opinions. At the outset, this Court notes that Dr. Taylor is the primary expert who relied on Purepac's data, and much of his expert testimony was excluded in this Court's Daubert opinions. However, to the extent this motion remains at issue, Plaintiffs' reliance on an interrogatory response produced by Defendants – one in which Defendants specifically reserved the right to supplement and amend its response as discovery, and particularly expert discovery, proceeded (Hedemann Decl., Ex. 8 at 2), – is misplaced. Plaintiffs have not cited any legal authority for the proposition that an interrogatory response can have the preclusive effect they seek here. See Phoenix Pinelands Corp. v. United States, No. 09-2237 (AET), 2010 U.S. Dist. LEXIS 40638, at *10 (D.N.J. Apr. 23, 2010). Additionally, Plaintiffs' claim of surprise and resulting prejudice is disingenuous. Dr. Taylor himself sets forth analysis in his expert report which indicates that the Purepac data is the result of relative humidity conditions that varied widely around the 50% mark set forth in Claim 7(ii). (Hedemann Decl., Ex. 25) Dr. Topp's responsive report was filed in May 5, 2010, and Plaintiffs had the opportunity to examine Dr. Topp about her opinions at her deposition. Having not previously objected, Plaintiffs cannot legitimately claim prejudice now, more than one year later.

[15] This motion is labeled as Plaintiffs' motion in limine number five.

[16] The cases Plaintiffs cite in support of this motion deal with assertions of attorney-client privilege in cases where the advice of counsel defense has been invoked and thus are not on point here. See In re Seagate Tech., LLC, 497 F.3d 1360, 1372 (Fed. Cir. 2007) ("The attorney-client privilege belongs to the client, who alone may waive it. The widely applied standard for determining the scope of a waiver...is that the waiver applies to all other communications relating to the same subject matter. This broad scope is grounded in principles of fairness and serves to prevent a party from simultaneously using the privilege as both a sword and a shield; that is, it prevents the inequitable result of a party disclosing favorable communications while asserting the privilege as to less favorable ones.") (internal quotations

Defendants only plan to use this evidence to rebut arguments by Plaintiffs that Defendants generally follow a practice of infringement and infringe in cases other than this one. Accordingly, this Court will reserve decision on this motion until the time Defendants seek to admit such evidence in order to determine if Plaintiffs have opened the door to its admission.

V. DISMISSAL AND NON-SUIT AS RELEVANT TO AVAILABILITY OF NON-INFRINGING ALTERNATIVES

Plaintiffs move to preclude Defendants' experts from offering opinions that various third parties likely developed non-infringing products based on the fact that Plaintiffs entered into stipulations of dismissal with those third parties or did not sue them for infringement.[17]

In order to prove entitlement to lost profits damages, a patent owner:

> must show that but for the infringing acts, the patent owner would have made the sales and would have made a certain level of profit. Four elements must be proved: (1) a demand for the patented product, (2) the absence of an acceptable, non-infringing substitute for the patented product, (3) the patent owner's manufacturing and marketing capability to exploit the demand for the patented product, and (4) the amount of profit the patent owner would have expected to make if the patent owner had made the infringer's sales.

Smithkline Diagnostics, Inc. v. Helena Laboratories Corp., 926 F.2d 1161, 1165 (Fed. Cir. 1991) (internal citations omitted) (emphasis added).

A. Geneva and Mutual

Geneva and Mutual are two generic producers of gabapentin who were originally sued as part of the instant multi-district litigation. On June 20, 2006, Judge Lifland granted summary

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omitted); In re EchoStar Communs. Corp., 448 F.3d 1294, 1303 (Fed. Cir. 2006) ("The overarching goal of waiver in such a case is to prevent a party from using the advice he received as both a sword, by waiving privilege to favorable advice, and a shield, by asserting privilege to unfavorable advice.").

[17] This motion is labeled as Plaintiffs' motion in limine number six.

judgment of non-infringement in favor of Geneva.[18] On June 28, 2006, Judge Lifland granted summary judgment of non-infringement in favor of Mutual.[19] However, Plaintiff settled with both Geneva and Mutual before a final judgment could be entered.[20]

Relying on Federal Rule of Evidence 408,[21] Plaintiffs seek a ruling that "[n]o inference should be permitted to be drawn" from their settlements with these two generic manufacturers.[22] Here, however, the jury will not be asked to draw any inference from Plaintiffs' settlement with Geneva and Mutual. Rather, it is the summary judgment decisions issued before the settlement was effected that are relevant to Defendants' contention that the Mutual and Geneva products were non-infringing alternatives.

To the extent Plaintiffs seek a ruling denying Judge Lifland's holdings on summary judgment evidentiary value, that application is denied. Judge Lifland's decisions were not vacated upon entrance of the stipulations of dismissal as to Mutual and Geneva, and Plaintiffs have not set forth any legal argument as to why Judge Lifland's holdings are no longer relevant.

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[18] In re Gabapentin Patent Litig., MDL No. 00-2931, Dkt. No. 342.

[19] In re Gabapentin Patent Litig., MDL No. 00-2931, Dkt. No. 344.

[20] On January 31, 2008, Plaintiffs and Mutual filed a "Joint Stipulation of Voluntary Dismissal." In re Gabapentin Patent Litig., MDL No. 00-2931, Dkt. No. 396. On February 20, 2008, Plaintiffs and Geneva filed a "Joint Stipulation of Voluntary Dismissal." In re Gabapentin Patent Litig., MDL No. 00-2931, Dkt. No. 400.

[21] This rule provides that evidence of settlement offers and negotiations "is not admissible on behalf of any party, when offered to prove liability for, invalidity of, or amount of a claim that was disputed as to validity or amount, or to impeach through a prior inconsistent statement or contradiction." The rule also provides, however, that it "does not require exclusion if the evidence is offered for purposes not prohibited by subdivision." Fed. R. Evid. 408.

[22] See Pltf. Br. 40-41.

Evidence of these decisions is admissible,[23] and the questions of how they weigh upon the presence or absence of non-infringing alternatives in the "but for" world and the subsequent question of appropriate lost profits damages are for the jury.

B. The Relevance of Settlements and Failures to Sue

In Pall Corporation v. Micron Separations, 66 F.3d 1211 (Fed. Cir. 1995), the Federal Circuit addressed the relevance of settlement with a potential infringer on the calculation of lost profits. The court wrote that "[t]he voluntary settlement of litigation does not retrospectively transform an accused infringing product into a 'noninfringing substitute.'" Id. at 1222-23. The Court went on to note, however, that after settlement, the products' "presence in the marketplace could not be ignored, and limited the award of lost profits" available to the patent holder to the share of the infringer's sales that the patentee would reasonably have made. Id. at 1223. This conclusion, the Federal Circuit reasoned, "implements the reasoning that the purpose of compensatory damages is not to punish the infringer, but to make the patentee whole." Id.

Similarly, in Abbott Diabetes Care Inc. v. Roche Diagnostics Corp., No. 05-03117 (MJJ), 2007 U.S. Dist. LEXIS 89251 (N.D. Cal. Nov. 19, 2007), a court in the Northern District of California applied Pall, concluding that "the relevance of the settlement agreement, under Pall Corp., is not dependent on whether the alterations to legal rights are classified as a 'license' or whether the settlement agreement sets for a basis for royalty calculations. Rather, the settlement agreement is relevant because it likely helps to explain why the LifeScan product[, which was the

[23] Defendants will not be permitted to use Judge Lifland's name in an effort to cloak the decisions with the authority and reputation those familiar with the Judge will likely attribute to him.

subject of the settlement] – and which products – can continue to be sold despite [Plaintiff's] earlier claims of infringement." Id. at *11.

As in Pall and Abbott, the terms of the settlement agreement and the presence on the market of potential gabapentin alternatives are relevant to the calculation of lost profits damages in this action. Similarly, the presence of potentially non-infringing alternatives on the market as a result of Plaintiffs' decision not to sue may alter the marketplace in a way that is relevant to lost profits. Plaintiffs' argument that the sales and production of these alternatives were so minimal as to be irrelevant goes to the weight of this evidence and not its admissibility.

VI. PLAINTIFFS' ORANGE BOOK LISTINGS AND THE '476 AND '479 PATENT LITIGATION

Defendants plan to introduce evidence as to the following three issues: (1) Pfizer's listing of Patent Nos. 4,894,476 (the '476 Patent)[24] and 5,084,479 (the '479 Patent)[25] in the Orange Book;[26] (2) Pfizer's suit against Defendants for infringement of both the '476 and '479 Patents; and (3) summary judgment of non-infringement of both patents.[27] Plaintiffs seek to preclude this evidence on the grounds that it is not relevant and is unfairly prejudicial.[28]

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[24] The '476 Patent covers the monohydrate form of gabapentin.

[25] The '479 Patent covers the use of gabapentin to treat neurodegenerative diseases.

[26] When a "New Drug Application" is approved by the FDA, the applicant must identify the patents it claims covers the drug. See 21 U.S.C. § 355(b). The FDA lists any patent disclosed in such an application in the FDA's "Orange Book."

[27] See Warner Lambert Co. v. Purepac Pharm. Co., Nos. 98-2749 (JCL), 99-5948 (JCL), 2003 U.S. Dist. LEXIS 24369, at *7-9 (D.N.J. May 21, 2003).

[28] This motion is labeled as Plaintiffs' motion in limine number seven.

Defendants argue that this evidence is relevant to both (1) the nexus between the '482 Patent and sales of Gabapentin and (2) the willful infringement inquiry.

A. Obviousness of the '482 Patent

"[S]econdary considerations such as commercial success" are relevant to the obviousness inquiry in an infringement suit. Ormco Corp. v. Align Tech., Inc., 463 F.3d 1299, 1311 (Fed. Cir. 2006).

"In order to overcome a finding of obviousness by demonstrating commercial success, '[a] nexus between commercial success and the claimed features is required.'" Therasense, Inc. v. Becton, Dickinson & Co., 593 F.3d 1289, 1299 (Fed. Cir. 2010) (quoting Brown & Williamson Tobacco Corp. v. Philip Morris Inc., 229 F.3d 1120, 1130 (Fed. Cir. 2000)). "'T]he asserted commercial success of the product must be due to the merits of the claimed invention beyond what was readily available in the prior art.'" Therasense, 593 F.3d at 1299 (quoting J.T. Eaton & Co. v. Atl. Paste & Glue Co., 106 F.3d 1563, 1571 (Fed. Cir. 1997)).

Courts have considered the applicability of other patents to a product in evaluating commercial success arguments. For example, in Merck & Co., Inc. v. Teva Pharmaceuticals USA, Inc., 395 F.3d 1364 (Fed. Cir. 2005), the court concluded that the commercial success of the drug at issue was of "minimal probative value" on the issue of obviousness. Id. at 1377. "Financial success is not significantly probative of [whether the claimed invention was non-obvious in light of prior art] in this case because others were legally barred from commercially testing the [relevant] ideas" by other patents claiming elements of the product. Id. Similarly, in Senju Pharmaceuticals Co. v. Apotex, Inc., 717 F. Supp. 2d 404 (D.Del. 2010), the court found that evidence of the commercial success of "ZYMAR®, the undisputed commercial embodiment

of the '045 patent" was of only "minimal probative value," in light of the fact that "others were legally barred from testing gatifloxacin products until the pediatric exclusivity associated with[a different] patent expires." Id. at 426.

Plaintiffs plan to introduce evidence of the commercial success of Neurontin. As set forth in Merck and Senju, the listing of the '476 and '479 Patents to cover Neurontin bears on the weight the jury should accord the commercial success evidence in evaluating obviousness.[29]

B. Willfulness

The Federal Circuit "fashioned a standard for evaluating willful infringement in Underwater Devices Inc. v. Morrison-Knudsen Co., 717 F.2d 1380, 1389-90 (Fed. Cir. 1983), 'Where . . . a potential infringer has actual notice of another's patent rights, he has an affirmative duty to exercise due care to determine whether or not he is infringing. Such an affirmative duty includes, inter alia, the duty to seek and obtain competent legal advice from counsel before the initiation of any possible infringing activity.'" In re Seagate Tech., LLC, 497 F.3d 1360, 1368-69 (Fed. Cir. 2007).

"[T]o establish willful infringement, a patentee must show by clear and convincing evidence that the infringer acted despite an objectively high likelihood that its actions constituted infringement of a valid patent. The state of mind of the accused infringer is not relevant to this objective inquiry. If this threshold objective standard is satisfied, the patentee must also demonstrate that this objectively-defined risk (determined by the record developed in the

[29] Plaintiffs will be permitted to seek a limiting instruction directing the jury as to the permissible use of this evidence. Any limiting instruction sought by either side must be submitted to this Court in accordance with the instructions set forth below.

infringement proceeding) was either known or so obvious that it should have been known to the accused infringer." Id. at 1371.

Defendants intend to introduce evidence that they did not infringe the '479 and '476 Patents in order to demonstrate a pattern of proper conduct with respect to Pfizer's intellectual property rights. Defendants rely upon GSI Group, Inc. v. Sukup Mfg. Co., 591 F. Supp. 2d 977 (C.D. Ill. 2008), in which the court found that "a pattern of copying competing devices without regard for any possible patent infringement....could support the conclusion that Sukup willfully infringed...." Id. at 983. Defendants argue that a pattern of proper conduct is similarly relevant here.

Plaintiffs have not cited any legal authority which supports barring this evidence. Instead, Plaintiffs argue solely that the introduction of this evidence will cause confusion for the jury, as it raises the specter of two patents that are related but not directly at issue in this action. The parties expect the jury in this case to understand complex concepts of chemistry and mathematics. Surely, then, they will also be able to distinguish between the three patents in question and will be able to properly assess the purpose of this pattern evidence. Accordingly, the evidence is admissible.[30]

VII. PH TESTING DONE BY DR. NORTHINGTON

Plaintiffs move to preclude testimony or argument regarding pH testing done by their expert, Dr. Northington, at Exova labs.[31]

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[30] Here too, Plaintiffs may seek a limiting instruction in accordance with the instructions set forth below.

[31] This motion is labeled as Plaintiffs' motion in limine number eight.

At Dr. Northington's September 29, 2010 deposition, he testified that he had done pH testing on gabapentin samples "early on in the project" at the request of counsel. (Hedemann Opp. Decl., Ex. 36) Dr. Northington indicated that he didn't recall the exact procedures used in the testing, did not review the results and could not remember why the results weren't included in his ultimate report. (Id.)

Following the deposition, Defendants sought an order directing Plaintiffs to produce the pH testing results generated by Dr. Northington. Plaintiffs produced a Certification by Dr. Northington in which he averred that he "did not consider the pH data and test results...in reaching any of the conclusions expressed in either of [his] expert reports" and had "not personally, through a designee, or through counsel communicated the pH testing and results...to any expert who is testifying in this case." (Dkt. No. 996) On the basis of this certification, Judge Shwartz denied Defendants' request to compel production of the pH testing and results. (Dkt. No. 998) Defendants did not appeal that ruling.

Plaintiffs now seek to preclude Defendants from questioning Dr. Northington about this pH testing on cross-examination. Defendants contend this questioning is relevant because if Dr. Northington did do pH testing and Plaintiffs chose not to disclose it, the jury may call into question the pH testing – done by other experts – that Plaintiffs are disclosing.

Defendants will be permitted to inquire as to whether Dr. Northington conducted pH testing and will be permitted to elicit testimony that he cannot recall much about that testing, but Defendants may not seek to impugn Dr. Northington or Plaintiffs for not turning over the results of this testing. Defendants did not appeal Judge Shwartz's ruling on their request to compel

production of the testing results and cannot now seek to suggest that there was an impropriety in not producing such test results.

VIII. LIABILITY INSURANCE AND INDEMNIFICATION

Defendants move to exclude evidence of (1) Teva's patent infringement liability insurance and (2) the April 26, 2004 Selective Waiver Agreement between Purepac and Teva, which includes Teva's agreement to partially indemnify Purepac for infringement liability.[32]

Federal Rule of Evidence 411 provides that "[e]vidence that a person was or was not insured against liability is not admissible upon the issue whether the person acted negligently or otherwise wrongfully. This rule does not require the exclusion of evidence of insurance against liability when offered for another purpose, such as proof of agency, ownership, or control, or bias or prejudice of a witness."

Plaintiffs seek to admit evidence of liability insurance and indemnification as relevant to the following three issues: (1) willfulness,(2) available, non-infringing alternatives, and (3) Teva's inducement of Purepac's infringement.

A. Willfulness and Available Non-Infringing Alternatives

Plaintiffs argue that this evidence is relevant to willfulness because it demonstrates that the risk of infringement "was either known or so obvious that it should have been known to the accused infringer." In re Seagate Tech., LLC, 497 F.3d 1360, 1371 (Fed. Cir. 2007). Use of evidence of liability insurance or an indemnification agreement[33] to establish that Defendants

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[32] This motion is labeled as Defendants' motion in limine number one.

[33] Indemnification agreements are treated like liability insurance under Rule 411. See e.g., In re Hanford Nuclear Reservation Litig., 534 F.3d 986, 1014 (9th Cir. Wash. 2008) ("Evidence of indemnification is generally inadmissible but may be used to show prejudice or

"acted...wrongfully" runs afoul of Rule 411. Plaintiffs do not cite a single case in which a court permitted the use of such evidence to establish willfulness.

Similarly, Plaintiffs' entire basis for seeking to use this evidence to demonstrate the availability of non-infringing alternatives as relevant to lost profits damages is limited to the argument that Defendants, "[r]ather than turning to alternatives that they contend were available to them, [] instead obtained insurance and indemnification to cover the risk."[34] Plaintiffs cite no legal authority in support of this assertion.

B. Inducement of Infringement

To prove inducement of infringement, "a patent holder must prove that once the defendants knew of the patent, they actively and knowingly aided and abetted another's direct infringement" and acted with "specific intent and action to induce infringement." DSU Med. Corp. v. JMS Co., 471 F.3d 1293, 1305 (Fed. Cir. 2006) (internal quotations omitted).

"'[A]n indemnification agreement will generally not establish an intent to induce infringement, but...such intent can be inferred when the primary purpose is to overcome the deterrent effect that the patent laws have on would-be infringers.'" MEMC Elec. Materials, Inc. v. Mitsubishi Materials Silicon Corp., 420 F.3d 1369, 1378 (Fed. Cir. 2005) (quoting Hewlett-Packard Co. v. Bausch & Lomb Inc., 909 F.2d 1464, 1470 (Fed. Cir. 1990)).

Here, Plaintiffs wish to use the Selective Waiver Agreement as evidence from which an inference can be drawn that Teva used the indemnification provision in that agreement to provide Purepac an incentive – i.e., protection from infringement liability – to enter the market, in

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bias of a witness.") (citing Fed. R. Evid. 411).

[34] (Pltf. Opp. Br. 5)

exchange for giving Teva permission to compete during the exclusivity period. Thus, evidence as to the indemnification agreement contained in the Selective Waiver Agreement is relevant to Plaintiffs' inducement of infringement claim.[35] Defendants may seek an appropriate limiting instruction pursuant to this Court's rules regarding a meet and confer to reach consensus as to the language of the instruction in advance such that side bar disputes can largely be avoided.

IX. DEFENDANTS' ESTIMATES OF POTENTIAL RISK EXPOSURE

Defendants seek to exclude evidence of their estimates of potential risk exposure in this litigation, including (1) internal documents estimating potential lost profits to Pfizer and (2) the September 2004 declaration of Terry Musika submitted in opposition to Plaintiffs' motion for a TRO and preliminary injunction.[36]

Defendants argue that the internal documents at issue – charts estimating sales of gabapentin produced in order to reach indemnity estimates – are irrelevant because they do not reflect a construction of the "but for" world, nor do they take into account available non-infringing alternatives which might preclude Plaintiffs from recovering lost profits damages. Defendants also contend that the introduction of this evidence is prejudicial because the jury will be confused and may reach the conclusion that Plaintiffs are entitled to lost profits because Defendants reached these estimates.

Similarly, Defendants argue that the Musika declaration presents conclusions based on an assumption of liability and entitlement to lost profits that the jury will have to reach before even

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[35] Plaintiffs make no argument that Teva's liability insurance is relevant to the induced infringement claim, nor could they do so based on the facts at bar.

[36] This motion is labeled as Defendants' motion in limine number two.

considering the amount of lost profits damages to be awarded. Terry Musika – an economic expert retained by Purepac – submitted the declaration at issue in conjunction with Judge Lifland's ruling on the preliminary injunction application. In reaching the conclusion that Plaintiffs' damages would be easily quantifiable – a factor that would then weigh against injunctive relief – Musika opined that, in the event there was a finding of liability, "the amount of consequential damages resulting from infringement could be easily determined under either a reasonably royalty or lost profits damage methodology." (Hedemann Decl., Ex. 8 ¶ 15) Musika also "calculated an assumed estimated lost profits damage award of $557 million based on Purepac's projected sales of gabapentin during the six months of Purepac's generic market exclusivity." (Id. ¶ 17)

These documents are relevant to the jury's decision as to the amount of lost profits damages to be awarded, if any. Defendants cannot walk away from their own documents and affidavits, and they are in a position to adduce testimony to explain these documents and affidavits or to mitigate their impact. The assumption/estimates/limitations of the documents affects the weight of this evidence but not its admissibility.

X. USE OF THE TERM "AT RISK"

Defendants move to preclude Plaintiffs from using the term "at risk" to describe the launch of Defendants' generic gabapentin products.[37]

Under the Hatch-Waxman Act framework, the launch of a generic drug is referred to as being "at risk" when it occurs before a final determination on infringement has been made. Here,

[37] This motion is labeled as Defendants' motion in limine number three.

Plaintiffs initiated the instant litigation on June 15, 2000, and Defendants began selling their gabapentin products in 2004.

Defendants argue that use of the term "at risk" creates confusion and prejudice because (1) the jury will equate the launch of their gabapentin products with "risky" behavior; (2) the jury might attribute knowledge of this risk to Defendants with regard to the willfulness inquiry; and (3) the description of third party non-infringing alternatives as launching "at risk" might detract from evidence that the alternatives did not, in fact, infringe.

The term"at risk" is commonly used in patent law and accurately describes the risk associated with the launches. See Novartis Corp. v. Teva Pharm. USA, Inc., No. 04-4473 (HAA), 2007 WL 1695689, at *30 (D.N.J. June 11, 2007) ("By its very nature, launching generic products 'at risk,' has risks."). Indeed, Defendants frequently refer to the launches of their products as "at risk" in their own internal documents, documents upon which Plaintiffs plan to rely at trial. Use of the term "at risk" at trial, then, is appropriate, and Defendants may introduce an appropriate definition of the term in their opening statements and in the jury instructions.[38]

XI. PLAINTIFFS' PLANT CLOSINGS

Defendants move to exclude evidence of the closing of two of Plaintiffs' manufacturing plants pursuant to Federal Rules of Evidence 402 and 403.[39]

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[38] Indeed, the parties should be able to reach a stipulation on an appropriate definition which this Court or counsel for the parties could then read to the jury.

[39] This motion is labeled as Defendants' motion in limine number four.

Federal Rule of Evidence 402 provides that "[a]ll relevant evidence is admissible, except as otherwise provided...." Federal Rule of Evidence 403 provides that relevant evidence "may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury, or by considerations of undue delay, waste of

To recover lost profits, "a patent owner must prove: (1) demand for the patented product, (2) absence of acceptable noninfringing substitutes, (3) his manufacturing and marketing capability to exploit the demand, and (4) the amount of the profit he would have made." Panduit Corp. v. Stahlin Bros. Fibre Works, Inc., 575 F.2d 1152, 1156 (6th Cir. 1978) (emphasis added).

Plaintiffs intend to offer the testimony of William Freckman, the former site manager of Plaintiffs' now closed Holland, Michigan and Groton, Connecticut plants, in order to establish that those plants had the capacity to continue to exploit demand for Neurontin in the "but for" world.

Defendants concede the relevance of the evidence about Plaintiffs' plants to these issues and propose to stipulate to Plaintiffs' capacity to produce Neurontin. Defendants cannot force Plaintiffs to stipulate to relevant facts simply because Defendants would prefer those facts not go before the jury. See e.g., Hill v. Wilson, 519 F.3d 366, 369 (7th Cir. 2008) ("Live testimony has value even when the defense prefers a paper substitute."); Parr v. United States, 255 F.2d 86, 88 (5th Cir. 1958) ("A party is not required to accept a judicial admission of his adversary, but may insist on proving the fact.") (internal quotations omitted).

While the fact of the plants' existence and closings are relevant and admissible, much of the evidence related to Plaintiffs' plants goes well beyond the scope of what is required to prove the elements of lost profits. In the Final Pre-Trial Order, Plaintiffs describe the job loss that resulted from the closings, as well as the important role the plants played in their communities and the charitable giving and education programs in which the plants participated. Plaintiffs

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time, or needless presentation of cumulative evidence."

have also included among their trial exhibits photos of the plants being demolished. This evidence does not relate to Plaintiffs' capacity to produce Neurontin in the "but for" world, nor to any other legal or factual issue the jury must decide. The probative value of this evidence is so negligible – if it has any at all – that it is clearly outweighed by the potential prejudice to Defendants should it be introduced.

Accordingly, Plaintiffs are permitted to introduce evidence of the capacities and existence of the Holland and Groton plants and of the dates of those plants' closures but are precluded from offering evidence about the job loss resulting from those closures, any charitable or educational programs in which the plants were involved, or photographic evidence of the demolition of the plants, pursuant to this Court's analysis under Federal Rules of Evidence 402 and 403.

XII. THE PARTIES' CONDUCT IN DISCOVERY

Defendants move to preclude Plaintiffs from introducing evidence of Defendants' alleged failure to comply with their discovery obligations pursuant to Federal Rules of Evidence 402 and 403.[40]

Plaintiffs complain that Purepac refused to produce samples of its product, asserting only that the product did not materially differ from what was outlined in its ANDA, and raised certain theories only during expert discovery.[41] Notably, Plaintiffs cited no case law in support of their contention that Defendants are not permitted to amend their theories during expert discovery.

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[40] This motion is labeled as Defendants' motion in limine number five.

[41] Based on the parties' briefs on this motion, it appears that much of the evidence at issue is included in Dr. Taylor's expert reports. This Court has excluded the bulk of Dr. Taylor's testimony in its two Daubert opinions.

If these issues posed problems during discovery – as Plaintiffs claim they did – Plaintiffs should have sought discovery sanctions at the appropriate time. To seek to adduce evidence at trial about claimed improprieties during discovery, without having sought and obtained discovery sanctions, would permit Plaintiffs to circumvent the deadlines for discovery motions and would inject extrinsic issues about discovery compliance into the trial.

Accordingly, Plaintiffs will be barred from introducing evidence of Defendants' alleged failures to comply with their discovery obligations.

XIII. PLAINTIFFS' SPENDING ON RESEARCH AND DEVELOPMENT

Defendants seek to preclude evidence of Plaintiffs' spending on research and development pursuant to Federal Rules of Evidence 402 and 403.[42]

Plaintiffs plan to offer evidence of their research and development efforts as (1) part of the description of their business and (2) relevant to both damages and to the validity of the '482 Patent.

A. Background Information

The background information Plaintiffs seek to offer, including evidence as to their research and development programs, is nearly identical to that proffered by Defendants, who also cite their research and development efforts in setting forth basic information about their businesses.

B. Damages and Validity of the '482 Patent

Plaintiffs' experts Dr. Beutel and Dr. Grabowski opine as to the role research and development plays in Plaintiffs' profit margins, which are directly relevant to the reasonable

[42] This motion is labeled as Defendants' motion in limine number six.

royalty negotiation[43] the jury may consider in the damages phase of the trial. Dr. Beutel opines, for example, that the parties to the hypothetical negotiation would have no overlapping negotiating range. This is, in his view, in part because Plaintiffs would need to recoup their research and development costs. The jury may consider Dr. Beutel's testimony and other evidence about Plaintiffs' spending on research and development should it need to determine a reasonable royalty. To the extent Defendants are concerned that the jury will be confused by this evidence and will seek to award Plaintiffs their costs in developing Neurontin, that concern will no doubt be cured by appropriate jury instructions as to how damages should be determined and the definition of a reasonable royalty.

Evidence of the research and development efforts made in developing Neurontin are also relevant to the patent's validity. For example, in Pfizer Inc. v. Teva Pharmaceuticals USA, Inc., No. 04-754 (JCL), 2006 U.S. Dist. LEXIS 74849 (D.N.J. Oct. 13, 2006), the court denied defendant's motion to preclude evidence of plaintiff's efforts to develop the drug at issue, finding the evidence relevant to the obviousness challenge to the patent.[44] Id. at *3-4 ("The Federal

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[43] A reasonable royalty "may be based upon an established royalty, if there is one, or if not, upon the supposed result of hypothetical negotiations between the plaintiff and defendant. The hypothetical negotiation requires the court to envision the terms of a licensing agreement reached as the result of a supposed meeting between the patentee and the infringer at the time infringement began." Rite-Hite Corp. v. Kelley Co., 56 F.3d 1538, 1554 (Fed. Cir. 1995) (internal citations omitted).

[44] Defendants rely upon Pfizer, Inc. v. Apotex, Inc., 480 F.3d 1348 (Fed. Cir. 2007). In that case, the district court considered as an indicia of non-obviousness that the plaintiff's "business decision to switch its commercial product" from one formulation to another, concluding that the research and development Pfizer had invested in the drug made the decision to make the switch extremely difficult. Id. at 1369. On appeal, the Federal Circuit concluded that "[t]he district court's reliance on this 'objective consideration' seems suspect as there is no evidence in the appellate record to support the implicit finding that Pfizer ever considered

Circuit has frequently focused on the unsuccessful attempts of the patentee in its obviousness analyses, and other courts have followed suit. For example, courts have considered inventors' extensive efforts and unsuccessful attempts to be probative of lack of suggestion or motivation to combine prior art, and the secondary consideration of failed attempts.") (internal quotations omitted); see also Novartis Pharm. Corp. v. Teva Pharm. USA, Inc., No. 05-CV-1887 (DMC), 2009 WL 3754170, at *19 (D.N.J. Nov. 5, 2009) (permitting plaintiffs "to present evidence with respect to the efforts put forth by the inventors to arrive at the contemplated invention" as relevant to the obviousness of the patent at issue). Here too, Plaintiffs may present this evidence in support of their position that the '482 Patent is not obvious.

XIV. REFERENCES TO "DEFENDANTS" AS A GROUP

Defendants move to preclude Plaintiffs from using the term "Defendants" when discussing issues or evidence pertaining to an individual Defendant.[45]

Defendants rely on Federal Rule of Evidence 105, which provides that "[w]hen evidence which is admissible as to one party or for one purpose but not admissible as to another party or for another purpose is admitted, the court, upon request, shall restrict the evidence to its proper scope and instruct the jury accordingly."

Plaintiffs must prove infringement as to each individual Defendant. However, Defendants' motion challenges the sufficiency of Plaintiffs' expert reports and other evidence in

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abandoning amlodipine or stood to lose significant time and investment dollars." Id. As a result, the Federal Circuit "disregard[ed] the district courts findings on this point as clearly erroneous, or in any event insufficiently probative of non-obviousness to overcome the evidence of the prior art teachings." Id. This holding – specific to the factual record at issue in that case – does not shed light on the motion at bar.

[45] This motion is labeled as Defendants' motion in limine number seven.

proving infringement.[46] The time for such a motion has passed. Defendants' challenges of Plaintiffs' experts should have been brought as Daubert motions, and their requests that the evidence on these issues be deemed insufficient should have been brought as summary judgment motions. Neither is appropriately the subject of a motion in limine.

While Defendants' motion on this point is denied, this Court cautions all counsel – and urges counsel to direct their witnesses – that they should use proper names of companies, people and positions in referring to the parties to this case and other relevant players. Because of the number of parties to this action, the use of the generic terms Plaintiffs and Defendants is insufficiently specific.

CONCLUSION

For the reasons set forth above,

IT IS on this 12th day of May, 2011,

ORDERED that the parties' motions in limine are **GRANTED** in part and **DENIED** in part, as follows:

1. Plaintiffs' motions to exclude evidence and arguments relating to (1) off-label promotion of Neurontin (Plaintiffs' Motion #1) and (2) Gabapentin's effectiveness in treating off-label conditions and Pfizer's alleged efforts to distort clinical trials (Plaintiffs' Motion #2) are **DENIED**.

2. Defendants' motion to exclude evidence and arguments contrary to prior courts' findings on the issues of off-label marketing and efficacy based on the doctrine of collateral estoppel (Defendants' Motion #8) is **GRANTED** in part and **DENIED** in part. Plaintiffs are estopped from denying their guilty plea and the factual basis for that plea..

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[46] Specifically, Defendants' challenge Plaintiffs' evidence as to (1) the stability of the accused products and (2) the level of anions of a mineral acid in API produced by Zambon and used in Defendants' products.

3. Plaintiffs' motion to exclude evidence and arguments that Purepac's capsules do not infringe because they contain silicon dioxide (Plaintiffs' Motion #3) is **DENIED** as moot.

4. Plaintiffs' motion to exclude evidence contrary to the positions Defendants took in discovery with regard to: (1) the construction of the "but for" world as it is relevant to lost profits damages and (2) Purepac's stability storage contentions (Plaintiffs' Motion #4) is **DENIED**.

5. This Court reserves decision on Plaintiffs' motion to exclude evidence that the Teva and IVAX Defendants relied on advice of counsel or followed a company policy of non-infringement in developing their gabapentin products (Plaintiffs' Motion #5).

6. Plaintiffs' motion to preclude Defendants' experts from offering opinions that various third parties likely developed non-infringing products based on the fact that Plaintiffs entered into stipulations of dismissal with those third parties or did not sue them for infringement (Plaintiffs' Motion #6) is **DENIED**.

7. Plaintiffs' motion to exclude evidence of (1) Pfizer's listing of the '476 and '479 Patents in the Orange Book; (2) Pfizer's suit against Defendants for infringement of the '476 and '479 Patents; and (3) summary judgment of non-infringement of both patents (Plaintiffs' Motion #7) is **DENIED**.

8. Plaintiffs' motion to preclude testimony or argument regarding pH testing done by Dr. Northington (Plaintiffs' Motion #8) is **GRANTED** in part and **DENIED** in part. Defendants will be permitted to inquire as to whether Dr. Northington conducted pH testing, but they may not rely on any extrinsic evidence in doing so, nor may they seek to impugn Dr. Northington or Plaintiffs for not turning over the results of this testing.

9. Defendants' motion to exclude evidence of (1) Teva's patent infringement liability insurance and (2) the April 26, 2004 Selective Waiver Agreement between Purepac and Teva (Defendants' Motion #1) is **GRANTED** in part and **DENIED** in part. All evidence of Teva's liability insurance is excluded. Evidence of the indemnification provision of the Selective Waiver Agreement is admissible only to the extent it is relevant to Plaintiffs' inducement of infringement claim.

10. Defendants' motion to exclude evidence of their estimates of potential risk exposure in this litigation, including (1) internal documents estimating potential lost profits to Pfizer and (2) the September 2004 declaration of Terry Musika (Defendants' Motion #2) is **DENIED**.

11. Defendants' motion to preclude Plaintiffs from using the term "at risk" to describe the launch of Defendants' generic gabapentin products (Defendants' Motion #3) is **DENIED**.

12. Defendants' motion to exclude evidence of the closing of two of Plaintiffs' manufacturing plants (Defendants' Motion #4) is **GRANTED** in part and **DENIED** in part. Plaintiffs are permitted to introduce evidence of the existence and capacity of the Holland and Groton plants and of the dates of closure of those plants but are precluded from offering evidence about the job loss resulting from those closures, any charitable or educational programs in which the plans were involved, or photographic evidence of the demolition of the plants.

13. Defendants' motion to preclude Plaintiffs from introducing evidence of Defendants' alleged failure to comply with their discovery obligations (Defendants' Motion #5) is **GRANTED**.

14. Defendants' motion to preclude evidence of Plaintiffs' spending on research and development (Defendants' Motion #6) is **DENIED**.

15. Defendants' motion to preclude Plaintiffs from using the term "Defendants" when discussing issues or evidence pertaining to an individual Defendant (Defendants' Motion #7) is **DENIED** subject to this Court's admonition that all counsel and witnesses should use proper names of companies, people and positions in referring to the parties to this case and other relevant players.

IT IS FURTHER

ORDERED that any party seeking a limiting instruction at trial must (1) meet and confer with the other parties for at least one hour and either reach agreement about the proper language to be used or jointly produce a dual-column chart setting forth the distinctions between each side's position on the proper instruction and (2) present the instruction or the chart to this Court

not less than 72 hours before the relevant evidence is expected to be used at trial;[47] and it is further

ORDERED that in light of the evidence excluded here and in this Court's April 25, 2011 Daubert rulings, the total time allotted for trial is reduced to 100 hours, with 50 hours allotted to each side.[48]

The Clerk of the Court is directed to terminate the motions: Dkt. Nos. 1084, 1085.

/s/ Faith S. Hochberg
Hon. Faith S. Hochberg, U.S.D.J.

[47] This requirement is necessary in order to prevent the drafting of limiting instructions at side bar and in light of the parties' demonstration up to this point that they do not take the "joint" meet and confer requirement sufficiently seriously. The Court is confident that this will be corrected as this arduous trial begins.

[48] Defendants may divide their time amongst themselves as they see fit but must confer and reach agreement as to how they plan to do so before trial. Any time that any one of Defendants' counsel is in control of the court room will be charged against Defendants' bank of 50 hours.